REMARKS

Objections to the claims

Claim 2 has been objected to as being improper for the recitation of contacting with a lipoheptapeptide at "higher than room temperature" because claim 1 previously limits the temperature to room temperature. Claim 2 has been amended to recite, "The method of claim 1, ~~wherein~~ **further comprising contacting** said product ~~is contacted~~ at temperatures higher than room temperature, ~~within~~ **for** a period of 5-30 min." With this amended, claim 2 has been clarified as having two treatment periods, one for 30 min. to 2 hours at room temperature, and a one at higher than room temperature for 5-30 min.

Claim 3 has been objected to as being unclear that "chemically synthesized lipopeptide" is separate from "a lipopeptide produced or modified by genetic engineering." Claim 3 has been amended as requested by the Examiner.

Claim 4 has been objected to for failing to further limit claim 1. Claim 4 has been cancelled and the dependency of claims depending from claim 4 has been amended to depend from claim 1.

Claim 18 has been objected to for containing a typographical error. Claim 18 has been amended to correct this error.

Rejections under 35 U.S.C.§112, 2nd paragraph

Claims 1-11 and 13-15 have been rejected under 35 U.S.C. §112, 2nd paragraph, as being unclear in the recitation of "a purified product isolated from blood or a biotechnologically produced product substantially free of lipid enveloped viruses." The Examiner asserts that the meaning of this term is not clear because the specification does not exclude cellular products. The Examiner suggests amending the claims to be limited to "isolated proteins." The claims have been amended as suggested by the Examiner. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-11 and 13-15 have been rejected as being unclear in the recitation of "by a factor of approximately $>10^4$" for two reasons.

a) The Examiner asserts that "approximately $>10^4$" is confusing because it is unclear what is meant by being approximately greater than a number. The claims have been amended to clarify this term and to recite "approximately 10^4 or greater."

b) The Examiner further asserts that the claims need to recite a viral titer of at least 10^4 because if the viral titer was lower than 10^4, the composition would have a negative viral titer. Applicants traverse this rejection and withdrawal thereof is respectfully requested. Applicants respectfully note that the Examiner is mathematically incorrect in his interpretation of the claim. If a starting 10^3 is reduced by a factor of 10^4, the resulting value is 0.1, not a negative value. As such, the claims are not internally inconsistent and withdrawal of the rejection is respectfully requested.

Claims 4-8 and 14 have been rejected for the recitation in claim 4 of the same lipoheptapeptides as recited in amended claim 1. Claim 4 has been cancelled, thus rendering this rejection moot.

Rejection under 35 U.S.C.§112, 1st paragraph

Claims 1-10, 13-15, 18 and 19 remain rejected under 35 U.S.C. §112, 1st paragraph, for lack of enablement. The Examiner maintains that the claims encompass the *in vivo* inactivation of viruses. The claim have been amended as suggested by the Examiner to be more clearly directed to in vitro products, with the

recitation of "at least one isolated protein." As such, withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C.§103

Claims 1, 3-7, 9, 10, 14, 15, and 18 have been rejected as being obvious over Itokawa et al., Chem. Pharm. Bull. 42(3):604-607, newly combined with Budowsky et al. (U.S. Pat. No. 6,114,108). Itokawa et al. is asserted to teach that surfactins from *B. subtilis* have antiviral activity. Itokawa et al. is also asserted to teach surfactin concentration within the claimed range. Itokawa et al. is asserted to differ from the invention in failing to teach the use of surfactins to render a composition of an isolated product substantially virus free. Budowsky is asserted to teach the use of anti-viral compounds to inactivate viruses in a composition such as blood.

In response to Applicants arguments, the Examiner asserts that obtaining 100% activation within 30 minutes to 2 hours is routine optimization. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

Itokawa et al. teach that surfactins isolated from *B. subtilis* moderately suppress the HIV-1 cytopathic effect, meaning the surfactins act on virus replication in cells.

Budowsky teaches that viruses can be inactivated in cell-containing or biopolymer-containing compositions with substances that are structurally unrelated to surfactins. In Budowsky, ethyleneimine oligomer reagents having an aziridino moiety are used. Virus inactivation in Budowsky is based on the selective chemical modification of nucleic acids contained in the compositions. One skilled in the art would not look to Budowsky nor have any motivation to combine the teachings in Budowsky with Itokawa because surfactins are not able to chemically modify nucleic acids as required by Budowsky.

In addition, the present invention possesses advantageous properties that are in no way suggested by or expected from the prior art. Itokawa et al. disclose on page 607, left column, 2nd paragraph, that "moderate anti-HIV activities" were observed for the surfactins. The XTT assay used in Itokawa et al. is described on page 579 of Weislow et al. J. Nat. Can. Inst. Vol. 81 No. 8, 577-586 (1989). According to the Weislow et al. article, in the XTT assay, the virus articles are exposed to the potential test compound for 7 days at 37°C. One skilled in the art would not expect effectively 100% inactivation after only at most 2 hours, given that Itokawa et al. teach only moderate inactivation after 7 days. In addition, since the viral in activation in Budowsky works by a specific and completely different and unrelated

mechanism than is achieved with surfactins, there is no expectation that surfactins would function in the method of Budowsky. The viral inactivation in Budwosky works specifically via nucleic acid modification, which surfactins are not capable of doing. As such, there is no motivation to use surfactins in the methods of Budowsky and the present invention is not obvious over the Itokawa combined with Budowsky.

Claims 2 and 13 have been rejected as being obvious over Itokawa combined with Naruse and Horowitz. The Examiner further rejects claims 8 and 11 over Itokawa et al., Naruse et al. and Vater et al. combined with Budoswky et al. The additional references of Naruse, Horowitz and Vater further fail to suggest that effectively 100% inactivation after only at most 2 hours could be achieved with the surfactins of the invention. As such, the invention is not achieved or suggested when Itokawa and Budowsky are further combined with Naruse, Horowitz and/or Vater. The invention of claims 2, 8, 11 and 13 is therefore not obvious over the cited references and withdrawal of the rejection is respectfully requested.

If any questions remain regarding the above matters, please contact Applicant's representative, MaryAnne Armstrong, PhD (Reg.

No. 40,069), in the Washington metropolitan area at the phone number listed below.

Pursuant to 37 C.F.R. §§1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a response in connection with the present application. The required fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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